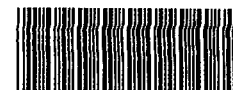
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Perchlorate

National Center For Environmental Assessment

The Effects of Ammonium Perchlorate on Thyroids Pathology Working Group Report



Cover Summary Memo

[PDF Version \(582K\)](#)

PWG Report with Cover Memo from EPL

[PDF Version \(112K\)](#)

ABSTRACT:

In response to recommendations made at the February 1999 external peer review of the December 1998 document entitled, Perchlorate Environmental Contamination: Toxicology Review and Risk Characterization (<http://www.epa.gov/ncea/perch.htm>), the National Center for Environmental Assessment (NCEA) arranged for a review of the thyroids from all of the studies by independent pathologists using a consistent lesion grading scheme and to then convene a pathology working group (PWG). The objective of this review was to perform a review by a second pathologist, that had not been performed for any of the individual studies, and which is traditionally accomplished before convening a PWG. Because of the potential for inconsistency across the studies due to the fact that the various studies had been performed by several different laboratories with several different study pathologists using different lesion grading systems, which made use of these data difficult for comparison and development of dose-response analyses, the purpose of the independent peer review and PWG was to decrease variability in response across the studies by providing a common nomenclature for lesions and a consistent pathology review.

After the initial pathology review of 100% of the thyroid slides by Dr. Douglas C. Wolf at the National Health and Environmental Effects Research Laboratory (NHEERL), Dr. Peter Maron of Experimental Pathology Laboratories, Inc. (EPL) reviewed 100% of the slides for quality assurance/quality control (QA/QC) and consistency. Subsequent to this QA/QC review of the independent peer review, a review by a pathology working group (PWG) of 5 experienced veterinary pathologists was conducted on a subset of the slides. Recommendations of that PWG (see The Effects of Ammonium Perchlorate on Thyroids, Pathology Working Group Report) were then incorporated into the final report on the independent review of 100% of the slides conducted and reported by Dr. Wolf (see Report of the Peer Review of the Thyroid Histopathology from Rodents and Rabbits Exposed to Ammonium Perchlorate in the Drinking Water). Both of these reports are now provided here as part of ongoing efforts to inform the assessment of risk due to perchlorate environmental contamination.

Determination of no-observed-adverse-effect levels was not the objective of this review. Such a determination requires the integration of diverse data from a variety of sources. It can be anticipated that the data from this review may result in different dose-response analyses to characterize the thyroid effects for the various studies. NCEA is coordinating these analyses for revised assessment due to be published for external peer review in the Fall. All data received by

June 30, 2000 will be the subject of this revised assessment. Other pieces of information important to the new analyses remain outstanding. Notably, an interlaboratory study of the variability in thyroid hormone analyses for these same studies was also conducted to decrease the variability of these measurements. This is another critical part of the dose-response analysis since the hormonal perturbations were considered to be causal for the thyroid changes and correlated to the histopathology in the analyses. Additional studies of the pharmacokinetics of ammonium perchlorate, and of its effects on the thyroids of dams and pups and on the neurobehavior and histopathology of pups, are also anticipated to inform this revised risk assessment. The thyroid histopathology from these studies will be reviewed according to the same criteria developed in these reports.



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